

REMARKS

Claims 1 to 6, 9 to 13, 32 to 39, 42, 44 to 48, 62, 69 to 72 and 74 to 76 are pending. Claims 1 to 6, 9 to 13 and 32 to 38 were withdrawn from consideration and have been cancelled. Claims 39 and 69 have been amended to correct a typographical error and to provide antecedent basis for a claim term so that the claims are in proper form for consideration on appeal. After entry of this Amendment claims 39, 42, 44 to 48, 62, 69 to 72 and 74 to 76 will be pending and under examination.

The Examiner has rejected claims 39, 42, 44 to 46, 48, 62, 69 to 72 and 74 to 76 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,643,296 to Hundertmark et al. (Hundertmark) in view of U.S. Patent No. 5,053,044 to Mueller et al. (Mueller). Applicants respectfully traverse this rejection.

Claims 39, 62 and 69 are the only independent claims under examination. Applicants submit these claims are allowable for at least the reasons set forth below. Each of the remaining claims depends from one of these independent claims and add further significant limitations which distinguish over the art and are allowable for at least the same reasons as the claim from which they depend.

In paragraph 4 of the Office Action the Examiner states with respect to claim 39 that Hundertmark, in FIG. 11, discloses a method of removing material comprising the steps of: delivering a catheter having a tissue debulking device or cutter 138; deflecting a distal portion of the catheter with respect to a proximal portion of the catheter to expose the cutter, wherein the proximal movement of the catheter through a tortuous blood vessel causes the deflection against an inner cam surface of the catheter. Applicants disagree with the Examiner's characterization of the method disclosed in Hundertmark.

Claim 39 is directed to a method of removing material from a body lumen and recites the step of “deflecting a distal portion of the catheter relative to a proximal portion of the catheter.” Claim 39 further recites that the deflecting step is “carried out by sliding the tissue debulking device against a cam surface”. This deflecting step is not disclosed or taught by Hundertmark, either alone or in combination with Mueller. In Hundertmark the deflection of the distal portion of the catheter with respect to the proximal portion of the catheter according to the method described in connection with FIG. 11 is caused by the catheter following the curved path of the blood vessel. Specifically, the deflection of the catheter in FIG. 11 of Hundertmark is carried out by advancing the catheter through the curved vessel resulting in the distal end of the catheter being deflected by the wall of the vessel to follow the path of the vessel. The deflection is not carried out by any sliding movement of cutter 138 against a cam surface. As a matter of fact the cam surface which the Examiner points out in the copy of FIG. 11 included in the Office Action appears to be the curved surface of the inner wall of the housing 140. However, that curved inner surface is not created until after the catheter has been deflected. Prior to the catheter being deflected by the vessel wall the curved cam surface to which the Examiner refers does not exist. Clearly, the deflection of the distal portion with respect to the proximal portion of the catheter in FIG. 11 of Hundertmark is not carried out by cutter 138 sliding against a cam surface. Since neither Hundertmark nor Mueller, alone or in combination, disclose the deflecting step claim 39 is allowable for at least that reason.

Claim 39 is also allowable for another reason. Claim 39 recites that the debulking step is “carried out by advancing the catheter in the body lumen to move the rotating tissue debulking device and cutting window through material in the body lumen during the debulking step”. The Examiner states with respect to claim 39 that Hundertmark is silent with regards to the step of advancing the

catheter in the body lumen to move the rotating tissue debulking device and cutting window through material in the deflecting step. The Examiner states, however, that the device shown in FIG. 11 is not secured to the region of stenosis and is capable of being moved through the body lumen of the blood vessel during the cutting process. The Examiner further states that Mueller discloses a similar device/method which includes moving the cutting element and the opening, together, in a forward direction to cut material in the blood flow lumen. The Examiner, therefore, concludes that one of ordinary skill in the art at the time the invention was made would modify the methodology of Hundertmark to include the method step of Mueller because it has been held that the use of a known technique (the step taught by Mueller) to improve similar devices (the device of Hundertmark) in the same way will yield predictable results. Further, the Examiner states it would be obvious to advance the device along the blood vessel while cutting if the region of stenosis is bigger than the cutting window. Applicants disagree and believe that the Examiner has misinterpreted Hundertmark.

Initially, Applicants submit that the Examiner's conclusion that the device shown in FIG. 11 of Hundertmark is not secured to the region of stenosis is incorrect. FIGS. 10, 11 and 12 show an embodiment of the Hundertmark device. FIGS. 11 and 12 are shown to illustrate use of the device in curved blood vessels. Portions of the device are clearly omitted in FIGS. 11 and 12 to show the position of the cutter within the device. However, as shown in FIG. 10, the device has structure which, although not labeled, appears to be the same as balloon 126 of

FIG. 1. This is consistent with the description of the function of balloon 126 in connection with FIG. 1 where Hundertmark states:

The balloon is inflated after the catheter 110 is positioned within a blood vessel. When the balloon 126 inflates, the balloon 126 pushes the window 142 of the housing 140 against the internal wall of the blood vessel. Atheroma, for example, are invaginated by the window 142 in this way (see FIGS. 11 and 12).

(Hundertmark, Col. 6, lines 59 to 65)(Emphasis supplied).

Therefore, Applicants believe that although the inflated balloon is not shown or described in connection with FIGS. 11 or 12 a person of skill in the art would understand from the entirety of Hundertmark that the device of FIGS. 10 to 12 has a balloon. The person of skill would further understand that inflation of the balloon would cause stenotic material SM to invaginate the window 142 when the device is used to remove SM from either inside or outside curves of vessels as shown in FIGS. 11 and 12. Therefore, Applicants believe the Examiner has misinterpreted the structure of the embodiment of FIG. 11.

Further, even if the device is capable of being moved through the lumen of the vessel during the cutting process as suggested by the Examiner a person of skill in the art would have no reason to use the Hundertmark device in that manner. As a matter of fact Hundertmark consistently describes the operation of the device as comprising rotating and axially translating the cutter 138 past the side window 142 to sever and remove stenotic material from an area of interest. (Hundertmark, Col. 6, lines 9 to 14; Col. 10, lines 43 to 50). In other words, the device is constructed so that once the cutting window has been pushed against the vessel wall to invaginate the window with atheroma the device and window remains in that position and the cutter is advanced past the window to cut the invaginated atheroma.

Applicants also disagree with the Examiner's conclusion that it would be obvious to modify the methodology of Hundertmark to include the method step of Mueller. In drawing this conclusion the Examiner indicates that the device disclosed by Mueller is similar to the atherectomy device disclosed in Hundertmark. Applicants submit that the devices are similar only in that they are both used at the site of stenotic lesions within a blood vessel. However, the manner of use is entirely different. Hundertmark is an atherectomy treatment device which cuts and removes the stenotic material from the wall of a vessel. Mueller is not an atherectomy device. Its use does not result in any material being removed from the blood vessel. Mueller is not a treatment device, at least by itself. It is a pretreatment device used in connection with angioplasty treatment. Specifically, the device of Mueller creates axial incisions within atheroma of a stenosed region in order to improve the success rate of subsequent balloon angioplasty treatment. (Mueller, Col. 2, lines 41 to 43). Therefore, Applicants disagree with the Examiner that it would be obvious to use a technique taught by Mueller to improve the device of Hundertmark. One skilled in the art would not be motivated to combine an atherectomy treatment device with a pretreatment device designed to prepare a vessel for subsequent balloon angioplasty.

This is especially true in consideration of the substantial structural differences in the devices. For example, the cutting blade of Mueller is substantially different from the cutter of the Hundertmark device as is the manner in which it is used. The cutting blade in the Mueller device appears to be substantially planar and does not rotate or axially translate. The blade merely pivots about a pin to extend outwardly through a slot to a position beyond the catheter sheath. In Mueller there is no need for atheroma to invaginate the slot through which the blade extends. Since the blade of Mueller does not axially translate with respect to the body of the catheter it is not capable of moving

through the lesion to make its incisions unless the entire catheter (and slot) is moved. The cutter of the atherectomy device disclosed in Hundertmark is substantially different. It is generally cylindrical, and rotates and axially translates with respect to the cutting window so only the cutter, not the cutting window, need be moved during the cutting process. This is significant since in Hundertmark the window is pushed against the vessel wall so that atheroma will invaginate the cutting window and the device is held in that position while the cutter is advanced past the window to cut the atheroma which has invaginated the window. Given these substantial differences there is no reason why a person of skill in the art would look to Mueller to modify the method of using the device of Hundertmark in the manner required by claim 39. Specifically, there is no reason why a person of skill in the art would move the cutter and the cutting window of Hundertmark through the atheroma together.

Further, Hundertmark emphasizes the importance of preventing the escape of the cutter through the cutting window (Hundertmark, Col. 4, lines 65 to 67; Col. 9, lines 34 to 43). They disparage prior art devices and methods which do not achieve this goal (Hundertmark, Col. 2, Lines 2 to 7). Clearly Hundertmark teaches away from use of devices such as disclosed in Mueller which have outwardly extending cutting blades. Therefore, a person of skill in the art would be directed by Hundertmark away from making this modification.

In view of the foregoing Applicants believe claim 39 is in condition for allowance. Claims 42, 44 to 46 and 48 depend from claim 39 and add further limitations which distinguish over the art and are allowable for at least the same reasons as claim 39.

Independent claims 62 and 69 are directed to methods which include the step of advancing a catheter having a cutter and a window (claim 62) or opening (claim 69) in a distal direction. In claim 62 the advancing step is done while “the

cutter and the window maintain their orientation with respect to one another when advancing the catheter”. Claim 69 recites that “the cutter and the opening maintaining their orientation with respect to one another when advancing the catheter”. In rejecting claims 62 and 69 the Examiner states that “the modification (to Hundertmark) to include the step of advancing the device through the occlusive material while the cutter is exposed is provided in the rejections to claims 39”. Applicants have discussed in detail above in connection with the rejection of claim 39 the reasons why a person of skill in the art would not modify the method of using the device of Hundertmark with the method disclosed in Mueller to move both the cutter and the cutting window together through the atheroma. Those remarks are equally applicable to the rejection of claims 62 and 69. Therefore, Applicants believe claims 62 and 69 are allowable for at least those reasons. Claims 70 to 72 and 74 to 76 depend from claim 69 and add further limitations which distinguish over the art and are allowable for at least the same reasons as claim 69.

The Examiner rejected claim 47 under 35 U.S.C. § 103(a) as being unpatentable over Hundertmark in view of Mueller and further in view of U.S. Patent No. 5,941,869 to Patterson et al. (Patterson). Claim 47 depends from claim 39 and adds further limitations to distinguish over the art and is allowable for at least the same reasons as claim 39.

The Examiner provisionally rejected claims 39, 42, 44 to 48 , 62, 69 to 72 and 74 to 76 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19 to 24 of copending Application No. 10/421979 and claims 1 to 15 of copending application No. 10/288581. Applicants will address this rejection when the Examiner indicates these claims are allowable.

It is believed that no fees are due in connection with this submission. However if this is incorrect, please charge any additional fees to Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

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